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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,885	07/30/2003	Karla Weaver	10123/00301	7939
30636 7590 11/21/2007 FAY KAPLUN & MARCIN, LLP 150 BROADWAY, SUITE 702 NEW YORK, NY 10038				
			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/630,885

Applicant(s)

WEAVER ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments, filed in the appeal brief (7/24/2007) with respect to claims 1-19 and 23-26 have been considered but are moot in view of the new ground(s) of rejection.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations recited in claim 6 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis for "the second slits" in claim 19.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-17, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,244,379). Smith discloses a valve apparatus (110) for medical applications comprising a first flexible disk (130) extending across a first lumen (114) through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements (either side of slit) formed on opposite sides of at least one slit (132) extending through the first flexible disk, the first moveable members being biased so that when a pressure from naturally occurring blood pressure is applied

to the disk the valve remains closed and when a pressure exerted by an outside pump is applied to the disk the valve opens to allow fluid to flow (see column 5, lines 34-57), wherein the slit is substantially linear and parallel to the axis of the disk, further comprising a housing (112) coupled to a catheter (122) with a sharpened distal tip for insertion into the lumen of a body, further comprising a biasing member (140) coupled to the first flexible disk and substantially parallel to the first slit, and wherein the first flexible disk is formed of silicone and is permanently sealed around the entire perimeter of the disk.

Claims 1-4, 8, 12, 14, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (2,720,881). Jones discloses a valve apparatus for medical applications comprising a first flexible disk (14) extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements (16) formed on opposite sides of at least one slit (middle part of 15) extending through the first flexible disk, the first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk and, when a pressure at least as great as the threshold value is applied to the first flexible disk, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen, wherein the first movable elements are biased toward the closed position by the resilience of the material of the first flexible disk, wherein the at least one first slit is substantially linear, wherein the substantially linear

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first slit is substantially parallel to a major axis of the first flexible disk, wherein the first flexible disk further includes a pair of second slits (sides of 15), each of the second slits intersecting a corresponding end of the first slit, further comprising at least one biasing member (4) coupled to the flexible disk and parallel to the slit, and wherein the disk is permanently sealed around the entire perimeter of the lumen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9-17, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (5,324,274) in view of Smith (4,244,379). Martin discloses a dual lumen catheter with two valve housings (42, 44) with rotary valves. Martin does not disclose a pressure actuated valve assembly. Smith discloses a pressure actuated valve assembly that only opens when the pressure in the patient is greater than in the vessel into which the fluid is being drawn. The Smith valve configuration is effective is

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preventing unwanted leakage and re-injection of the withdrawn fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the valve assembly of Martin with the valve configuration of Smith to avoid leakage and re-injection of fluid that can be caused by human error associated with rotary valves (mistakenly leaving the rotary valve open).

Claims 8 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (5,324,274) and Smith (4,244,379) in further view of Jones (2,720,881).

Martin and Smith together disclose all of the limitations recited in claims 3 and 15.

However, they do not disclose a pair of second perpendicular slits intersecting the first slit. Jones teaches such a configuration and teaches that this configuration is useful in pressure actuated valves. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Martin and Smith with the valve configuration of Jones to make an improved pressure actuated valve.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, 23-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-12, 15-16, 18-34 of copending Application No. 10608660. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations do not pass the threshold for being patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 7,252,652 to Moorehead discloses a similar invention but does not qualify as prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
**NICHOLAS D. LUCCHESI**  
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